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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,917	02/17/2004	Nancy Allbritton	60021010-0034	8995

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,917	ALLBRITTON ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because the applications identified on page 2 and for which Applicants claim benefit under 35 USC §119(e) are utility (non-provisional) applications. Benefit of these applications may be claimed under 35 USC §120 (lower portion of page 2) if the conditions of the statute are met (see MPEP § 201.11).

Specification

The specification is objected to for the following reasons. In the section entitled "Cross Reference to Related Application," Applicants state that the instant application is a divisional of parent Application No. 09/859,650 (now US Patent No. 6,740,497). The instant application is a continuation, not a divisional, as the claims do not read on an invention that was not elected in the parent application. Appropriate correction of the priority information is requested.

Additionally, this application contains sequence disclosures at page 26, 49-50, and 60 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(l) and (a)(2). The application fails to comply with one or more of the requirements of 37 CFR §§1.821 through 1.825 for patent applications containing nucleotide sequence and/or amino acid sequence disclosures. Although an examination of this application on the merits can proceed without prior

compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete. Failure to comply will be deemed nonresponsive. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-61 are rejected under 35 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described the specification such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, claims 54 and 61 recite substrate molecules for an oncoprotein. This claim language encompasses a multitude of possible substrate molecules, including substrates neither contemplated nor disclosed by the specification as filed. Applicants have not provided any description, sequences or structures for any oncoprotein substrates to be used in the claimed methods. Applicants have also not provided any guidance for identifying or preparing such substrates. In view of the great extent of the claimed subject matter, combined with the fact that the specification as filed provides no description of any oncoprotein substrate molecules (see the prophetic

example on p. 61, line 10, to p. 62, line 12 of the specification), it is clear that at the time of filing the application, Applicants were not in possession of the claimed invention. Thus, a holding of failure to meet the written description requirement is required.

Claims 54-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed above with respect to the written description requirement, claims 54 and 58 recite substrate molecules for an oncoprotein. As also discussed above, this claim language encompasses a multitude of possible substrate molecules for an oncoprotein, including compounds neither contemplated nor disclosed by the specification as filed and for which Applicants have provided no guidance as to the structure or identity of the claimed substrates or as to methods for their preparation. In view of the great extent of the claimed subject matter, combined with the fact that the specification as filed provides a description of only a limited amount of guidance (an oncogene to be used in the assay, the bcr/abl tyrosine kinase that is associated with CML), it is clear that in order to practice the scope of the claimed subject matter, the artisan of ordinary skill would have expected to have undertaken essentially a trial and error process. Such a process clearly amounts to undue experimentation. Because the specification provides no guidance as to the oncogene substrate to be made and the methods by which such substrate would be made, the skilled artisan clearly would have

expected to have to experiment unduly to practice the claimed invention. In sum, undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth the claims (In re: Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A holding of non-enablement is, therefore, clearly required.

Additionally, claims 54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure. Claim 54 recites a method of detecting cancer, comprising measuring the presence of oncogenic activity (claim 54). Oncogenic activity, as measured by detecting the enzymatic activity of a protein encoded by an oncogene, is not necessarily a sign of cancer. A cell in which an oncogene is expressed is not necessarily a malignant cancer cell. As noted in the 1996 Internet publication from the NIH Cancer Research Website, the abl oncogene is present in normal cells and activated in CML patients after it is transferred from chromosome 9 to chromosome 22. Bcl-2 oncogene activity is associated with apoptosis, and p53 activity functions in tumor suppression (see Cancer Research: Because lives depend on it, http://rex.nci.nih.gov/massmedia/CANCER_RESRCH_WEBSITE/CANCER_RESRCH_MAIN.htm, printed from the Internet on Sep. 9, 2004, middle of p. 2 and top of p. 3). Also, as noted in Weinberg, Cell 30(1):3-4, 1982, oncogenes play a normal role in animal cell physiology and acquire a malignant role following a rare event such as

recombination with a retroviral genome (see p. 3, paragraphs 4-7). Thus, measuring the presence of oncogenic activity for a particular oncogene may be an indication of cancer, but measuring the activity of any oncogene will not necessarily detect cancer. Among oncogenes, the specification discloses measuring only bcr-abl tyrosine kinase activity, which is associated with chronic myelogenous leukemia. Further, even if the activity of an oncogene protein product that is associated with cancer is detected in a cell or cells, it does not mean that the subject whose cells were analyzed will develop cancer or has cancer. It is an indication, though, that the subject has an elevated risk of developing cancer. The claims may be amended to recite, for example, a method of detecting an increased risk of cancer (claim 54).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 54 and 58 are incomplete. These claims are drawn to a method of detecting cancer and a method of testing a compound for anti-cancer activity, but the claim recitations end with the step of determining the presence of a chemical reaction. There is no recitation that relates the result to the preamble. Claim 54 may be amended to recite, for example, ... determining the presence of said chemical reaction from the presence of modified substrate molecules, wherein the presence of modified substrate molecules is indicative of an increased risk of cancer.

Claim 58 may be amended to recite, for example, ... determining the presence or absence of said chemical reaction from the presence of substrate molecules or the presence of altered substrate molecules; and comparing amounts of substrate molecules or altered substrate molecules to those from a cell or cells not exposed to the compound, thereby determining the anti-cancer activity of the test compound. The method of claim 58 as written, even if complete, would test for a compound that has no anti-cancer activity, as one of the steps is determining the presence of the chemical reaction that occurs in cancer cells and distinguishes them from normal cells. Also, it is noted that the last (7^{th}) step of the method recites "modified" substrate molecules. The rest of the claim recites "altered" substrate molecules. It is not clear whether or not modified and altered substrate molecules are the same or different. If they are different, it is not clear what the difference is, rendering the metes and bounds of the claim unclear. Therefore, a holding of indefiniteness for claims 54-61 is required.

Double Patenting

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of U.S. Patent No. 6,740,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending application and the issued patent claim the same method of measuring the presence of oncogenic activity in which labeled substrate molecules are put into a cell and allowed to react. The labeled substrate and altered (reacted) labeled substrate molecules are then liberated from the cell, and the presence of each is detected. In the instant application, the preamble of claim 54 recites a method of detecting cancer, comprising measuring the presence of oncogenic activity in a cell, while in the issued patent, the preamble of claim 1 recites a method for measuring the presence of oncogenic activity in a cell. In the instant application, claim 56 recites that the amount of detected altered or unaltered substrate is quantified. In the issued patent, the preamble of claim 16 recites a method for measuring and quantifying the presence of oncogenic activity in a cell. Although the preamble of instant claim 54 recites what the measurement of oncogenic activity may be used for, this is not a patentable distinction, as, in each case, the same method is used to measure oncogenic activity in a cell. One of ordinary skill in the art would have recognized that, where the activity of a particular oncogene is known to be related to malignant cancerous cell growth, the method of the parent issued patent would have been applied for the detection of cancer in a cell or cell sample by measuring the activity

of that oncogene.

Similarly, the method of instant claim 58, with one extra, initial step recites the same method as claim 1 of the issued patent, and claim 60, with one extra, initial step, recites the same method as claim 16 of the issued patent. The initial step in each case is that the cell or cells are exposed to a test compound, and then the presence of oncogenic activity is determined. Claims 58 and 60 are drawn to a method of testing a compound for anti-cancer activity. One of ordinary skill in the art would have recognized that, in screening for a compound with a certain pharmaceutical property, such as the ability to inhibit or enhance a certain chemical reaction, a cell or a sample of cells would have been exposed to the test compound and then used in an assay method that detected whether or not that chemical reaction still occurred (see, e.g., Bissery, US 5,728,687, column 2, lines 40-63, and column 3, which discloses a method for determining the killing activity on tumor cells of several anti-cancer drugs, in which cells are exposed to the drugs and the degree of cell killing is then determined). Therefore, there is no patentable distinction between instant claims 58-61 and claims 1 and 16 of the issued patent.

Because the inventions were commonly owned at the time that the invention in this application was made, a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999 may be obviated by filing a terminal disclaimer.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

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2004-09-14

FRANCISCO PRATS
PRIMARY EXAMINER